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10/779,978	02/17/2004	Peter M. Bonutti	782-A03-024	9101

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EXAMINER

MASHACK, MARK F

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/779,978	Applicant(s) BONUTTI ET AL.	
	Examiner MARK MASHACK	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5,7,8,10,14,24,25,35-39,43-46,48 and 52-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5,7,8,10,14,24,25,35-39,43-46,48 and 52-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to a communication dated 11/15/2010. Claims 2-5, 7-8, 10, 14, 24-25, 35-39, 43-46, 48, 52-58 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/15/2010 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claim 25** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed limitation "a biasing element biasing the elongate sleeve in the first sleeve portion, the biasing member imparting a

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compressive force on the retainer received between the first and second compression elements". The specification does not support the elongate sleeve imparting the compressive force.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claim 37** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. "The first sleeve position" is defined as a position of the "elongate insulating sleeve" in the independent claim. It is unclear how the "tubular member" is moved to the position of the sleeve.

6. **Claim 59-61** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim language "the second member include[es] an elongated insulation sleeve" and "the insulation sleeve moves independently of movement of the body of the second member" is indefinite because it is unclear how a component of the second member moves relative to the second member.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 2, 4-5, 7-8, 10, 14, 24, 35-38, 44-46, 59-61** rejected under 35

U.S.C. 102(b) as being anticipated by **Yoon (US 5,908,429)**.

Regarding Claim 14, 24, 44, 59-61 Yoon discloses of a device comprising:

a first member including a compressive element **538, 550a**;

a second member **536** including a proximal and a distal end, the distal end having a gapped portion **560** with a second compression element **550b** being integrated into the gapped portion, wherein the tubular second member is movable along a linear path relative to the first member from a first position to a second position, and wherein the first compression element and the second compression element are capable of receiving a retainer therebetween (Col 21, Line 62, - Col 22, Line 16);

an energy source operably connected to the first compression element (Col 21, Lines 57-61 and Col 8, Lines 57-59); and

an elongated insulation sleeve **512** controllably positionable over the tubular second member (Col 8, Lines 44-47), the elongated sleeve further comprising a collar member (proximal collar as labeled **22** in Fig 1), capable of receiving an end portion of a suture, wherein the insulation sleeve **512** is capable of insulating the suture attached to the collar member from energy from the energy source (Col 8, Lines 51-59).

Regarding Claim 35, the insulation sleeve is controllable positioned over the gapped portion and the sliding is independent of the tubular member and an on/off switch is inherent which also serves also a “safety switch” capable of preventing delivery of energy to the gapped portion of the tubular member when the insulation

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sleeve is in the second position. **Regarding Claim 36**, a retainer is capable of being received between the first and second compression elements. **Regarding Claims 37**, the actuating member **540** is capable of moving the tubular member from an open and a closed position. **Regarding Claims 2, 38**, a bias member biases the tubular member into the first sleeve position (Col 22, Lines 9-13). **Regarding Claims 45-46, 4-5, 7-8, 10**, the first compression element **550a** can emit ultrasonic energy and is considered an ultrasonic horn since it can do so (Col 2, Lines 62-65).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. **Claims 3, 39, 48** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Yoon**.

Yoon discloses that the bias member is intended to “cut anatomical tissue” when actuated (Col 22, Lines 13-16). **Yoon** is silent on the compressive force. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum range or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

12. **Claims 25, 43** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Yoon** in view of **Vancaillie (US 5,980,520)**.

Yoon discloses all of the claimed limitations except for the insulation sleeve being biased over the first and second members. However, **Vancaillie** teaches that it is commonly known in the art at the time of the invention to bias an energy transmitting member into a protective sheath (Col 1, Lines 19-34). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of **Yoon** with the biasing member biasing the first and second members inside of the insulation sleeve in order to prevent inadvertent tissue damage during delivery.

13. **Claims 52-53, 55, 57-58** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Yoon** in view of **Bates et al. (“Bates” US 6,348,056)**.

Yoon discloses all of the claimed limitations except for the proximal end of the elongated insulation sleeve including a channel for engaging a pin positioned on the second member, and wherein the channel and the pin cooperate to control a range of motion of the sleeve over the second member. However, **Bates** teaches that it is

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commonly known in the art at the time of the invention to controllably move an instrument within a sleeve **12** by providing a pin **18** on the instrument and a groove **14** on the sleeve (FIG 11). All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Bates**, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of **Yoon** with a pin and groove. Doing so would provide an easy way to provide relative motion between the sheath and instrument.

14. **Claims 54, 56** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Yoon** in view of **Vancaillie** as applied to **Claims 25 and 43** further in view of **Bates et al.** ("**Bates**" US 6,348,056).

Yoon in view of **Vancaillie** discloses all of the claimed limitations except for the proximal end of the elongated insulation sleeve including a channel for engaging a pin positioned on the second member, and wherein the channel and the pin cooperate to control a range of motion of the sleeve over the second member. However, **Bates** teaches that it is commonly known in the art at the time of the invention to controllably move an instrument within a sleeve **12** by providing a pin **18** on the instrument and a groove **14** on the sleeve (FIG 11). All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known

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methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Given the teachings of **Bates**, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of **Yoon** in view of **Vancaillie** with a pin and groove. Doing so would provide an easy way to provide relative motion between the sheath and instrument.

Response to Arguments

15. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is (571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 3773

/Darwin P. Erez/
Primary Examiner, Art Unit 3773